ProCare Service Test Procedure

REV.	ECO	DATE	DESCRIPTION
A	MR37676	05 Aug 02	Initial Release

1.0 SCOPE

This document specifies the operational test procedure for the DINAMAP ProCare Series Monitors.

This procedure establishes test steps required to run operational tests. When these steps are properly performed, the process will certify proper performance of the Unit Under Test (UUT) or it will identify those portions of the test, which the unit failed.

All tests may not be applicable to models without specific options, in which case those tests shall be omitted. It should be noted which options are available during the test setup.

2.0 PURPOSE

To provide a level of operational test sufficient for field returned units after the repair process.

3.0 APPLICABLE DOCUMENTS

2009511 Sunshine Unit Level Test

4.0 REQUIRED EQUIPMENT

Safety tester
Hi Pot Tester
DMM (Fluke 8842 or equivalent)
NIBP Analyzer (DNI Nevada "Cuff link" or Equivalent)
Manometer Digital 0-600mmHg Range or equivalent
Adult BP Cuff, Adult hose, and mandrel
Inflation bulb and associated tubing
Calibration Kit, p/n 320246 available through GE Medical Systems
SPO2 Simulator (for appropriate SPO2 type if SPO2 is installed)
SPO2 Cable (for appropriate SPO2 type, if SPO2 is installed)
TE 1811 Temperature Probe Simulator (if TEMP is installed.) The Temperature Probe Simulator for the Alaris System is available from Alaris Medical Systems, Inc. (619) 458-7000
Printer Paper (Part Number 089100)
Temp probe Hi Pot Adapter (Temp probe assembly with probe removed and probe cable leads shorted and attached to connector compatible with Hi Pot Tester.)

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SPO2 probe Hi Pot Adapter (DS100A or disposable sensor with purple DB9 connector with sensor removed and probe cable leads shorted and attached to compatible connector for Hi Pot Tester)
PC with Host Communications emulator (Hyperterminal or equivalent) (Cable Pin out see appendix B)

Complete the Test Record (Appendix A) as tests are performed.

Note: This test is written so that a knowledgeable technician who is familiar with the *ProCare* monitor and the test equipment will be able to follow the test procedure.
Note: To enter "service" mode press and hold the CYCLE button while pressing the ON/OFF button.
Note: To enter "bug" mode press and hold the ALARM and HISTORY buttons while pressing the ON/OFF button

Notes on Electrical Safety Testing of the *ProCare* Monitor:

The DINAMAP® *ProCare* Monitor is designed and tested to meet electrical safety standard IEC60601-1. Requirements in this standard parallel requirements in NFPA99 relating to electrical safety. This product meets the requirements of NFPA99 section 7-5.1.2.2. (grounding of appliances) through the use of double insulation in the external power supply module ("Power Brick".)

The absence of a ground connection on the Power Brick obviates the need for any ground resistance test, such as that described in NFPA99 section 7-5.1.3.2. (Some non-USA Power bricks are equipped with a non-conductive Safety Testing pin at the ground pin location to aid mechanical retention of the Power Brick into the receptacle.) Dielectric strength ("Hi-Pot") testing of the double (reinforced) mains insulation (4000 V RMS, 60 Hz) may be done by disconnecting the Power Brick from the Monitor and applying the Hi-Pot tester as follows: Connect one lead to the ground pin location to aid mechanical retention of the Power Brick into the receptacle. Connect the other lead to the conductive sleeve on the DC output connector at the end of the cord. Hi-Pot testing of the patient connections (1500 VRMS, 60 Hz) may be done by connecting one lead of the Hi-Pot tester to the outer shell of a spare DC connector plug inserted into the DC input connector on the Monitor. The other lead of the tester should be connected to the patient connection being tested.

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NOTE: Hi-Pot testing is done on every unit at the factory and should not be repeated unnecessarily nor performed more often than required. (If unit is opened for repair Hi-Pot testing is required)

5.0 Temperature Circuit Hi-Pot Test

5.0.1 Plug temperature probe Hi Pot adapter into the temperature connector.
5.0.2 Setup the Hi Pot tester for test at 1800 Volts AC for 1 second (alternate test 1500 Volts AC for 1 minute)
5.0.3 Set tester for current limit to 1 mA.
5.0.4 Connect the positive lead of the tester to the temperature probe Hi Pot adapter.
5.0.5 Connect the negative lead of the tester to the ground post of the DC input connector.
5.0.6 Start test
5.0.7 Verify unit passed test.

5.1 SPO2 Circuit Hi-Pot Test

5.1.1 Plug SPO2 extension cable into the SPO2 connector on the front of the unit.
5.1.2 Plug SPO2 probe HI Pot Adapter into the DB9 connector at the end of the SPO2 extension cable.
5.1.3 Setup the Hi Pot tester for test at 1800 Volts AC for 1 second (alternate test 1500 Volts AC for 1 minute)
5.1.4 Set tester for current limit to 1 mA.
5.1.5 Connect the positive lead of the test to the SPO2 probe Hi Pot adapter.
5.1.6 Connect the negative lead of the tester to the ground post of the DC input connector.
5.1.7 Verify unit passed test.

5.2 Temperature Circuit Leakage Test

5.2.1 Setup an IEC 601-1 approved leakage tester to apply 240 VAC to an isolated circuit. (Alternate method 120 VAC max 75 uA)
5.2.2 Plug temperature probe Hi Pot adapter into the temperature jack.
5.2.3 Record and verify the temperature circuit leakage current.

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5.3 SpO2 Circuit Leakage Test

5.3.1 Setup an IEC 601-1 approved leakage tester to apply 240 VAC to an isolated circuit. (Alternate method 120 VAC max 75 uA)
5.3.2 Plug a SpO2 cable into the SpO2 connector on the front of the unit.
5.3.3 Plug SpO2 probe Hi Pot adapter in to the DB9 jack at the end of the SpO2 cable.
5.3.4 Record and verify the SpO2 circuit leakage current.

5.4 Patient Monitor Parameter Tests

Complete the Test Record (Appendix A) as tests are performed.
Note: This test is written so that a knowledgeable technician who is familiar with the *ProCare* monitor and the test equipment will be able to follow the test procedure. To enter service mode press and hold the CYCLE button while pressing the ON/OFF button.

Burning Changes into Flash Memory: While in service mode, for modifications made to the Monitor's calibration and/or configuration to become permanent, they must be burned into the Monitor's flash memory prior to exiting this mode. This process does not need to be performed after every change but only once prior to exiting service mode.
Two steps are necessary for burning changes into flash:
1. Press the **CYCLE** button until 6 is displayed in the **min** window
2. Press and hold the **MENU** button until two beeps are heard (one when the button is pressed and another after the button has been depressed long enough for the process to complete. The number of times the flash memory can be burned is limited. The fatal alarm error **975** may be issued after this process is performed more than 90 times. Following issuance of this fatal alarm, the monitor must be returned to the GE Medical Systems *Information Technologies* Service Center to reset the flash memory so that future burns can be performed

Recommend re-flash of the memory if number of available flashes is below 50.

5.5 SETUP

5.5.1 Connect your NIBP Analyzer to the *ProCare* Monitor.
5.5.2 T' an inflation bulb into the pneumatic setup
5.5.3 Consult the following diagram for pneumatic setup guidelines.

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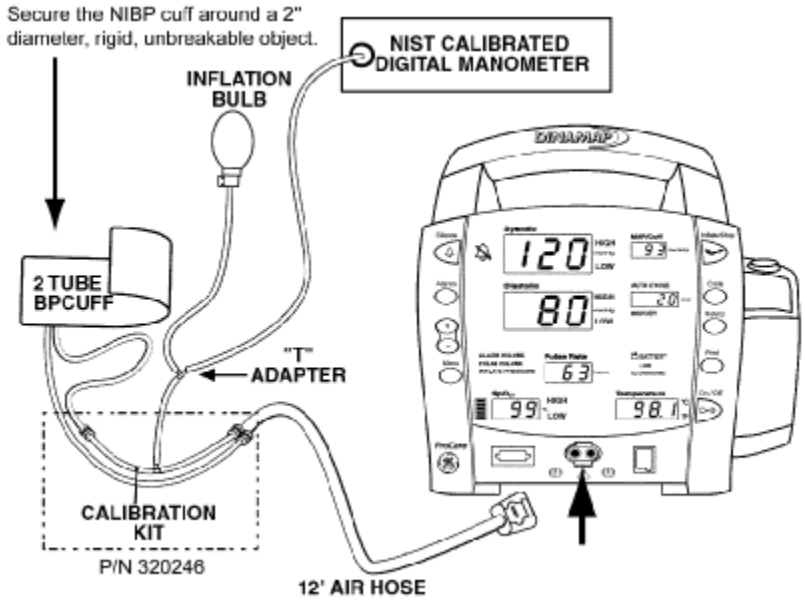

5.6. Leakage Testing

Note: To enter service mode press and hold the CYCLE button while pressing the ON/OFF button.

5.6.1 Turn the Monitor ON and enter Service Mode.
5.6.2 Press **CYCLE** button and the **min** display should change to a 1.
5.6.3 Close the valve on the inflation bulb.
5.6.4 With Inflation bulb manually inflate the system to 200mmHg.
5.6.5 Wait 10 seconds for stabilization of system.
5.6.6 Monitor leakage rate for 60 seconds.
5.6.7 Record and verify the leakage rate.
5.6.8 Turn the ProCare Monitor off.

5.7 Pressure Transducer Verification *

Note: To enter service mode press and hold the CYCLE button while pressing the ON/OFF button.

5.7.1 Turn unit ON and enter Service Mode.
5.7.2 The **min** window should display **0**.
5.7.3 Set NIBP Analyzer to "Manometer" function and press "Zero Pressure" or use a Digital manometer.

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5.7.4 Press CYCLE button, **min** display should change to a 1.
5.7.5 Use the inflation bulb to inflate the cuff, hose and pressure indicator setup to 200mmHg.
5.7.6 Record and verify the pressure reading on the top LED display (SYSTOLIC).
5.7.7 Record and verify the pressure reading on the bottom LED display (DIASTOLIC).
5.7.8 Use the valve on the bulb to reduce pressure to 150mmHg.
5.7.9 Record and verify the pressure reading on the top LED display (SYSTOLIC).
5.7.10 Record and verify the pressure reading on the bottom LED display (DIASTOLIC).
5.7.11 Use the valve on the bulb to reduce pressure to 100mmHg.
5.7.12 Record and verify the pressure reading on the top LED display (SYSTOLIC).
5.7.13 Record and verify the pressure reading on the bottom LED display (DIASTOLIC.)
5.7.14 Use the valve on the bulb to reduce pressure to 50mmHg.
5.7.15 Record and verify the pressure reading on the top LED display (SYSTOLIC).
5.7.16 Record and verify the pressure reading on the bottom LED display (DIASTOLIC.)

*****If any of the tests fail, continue to section 5.8. Otherwise, continue to section 5.9.

5.8 Pressure Transducer Calibration

Perform only if Pressure Transducer Verification is out of tolerance as specified in Appendix A.

Note: To enter service mode press and hold the **CYCLE** button while pressing the **ON/OFF** button.

5.8.1 Turn the ProCare Monitor **ON** and enter Service Mode.
5.8.2 The **min** window should display **0**.
5.8.3 Open valve on bulb to open pressure system to atmosphere.
5.8.4 Set NIBP Analyzer to "Manometer" function and press "Zero Pressure" or use a Digital manometer.
5.8.5 Press **CYCLE** button until the **min** window shows 1.
5.8.6 Close valve on bulb and manually inflate pressure to 200 mmHg (using the CuffLink manometer as reference or manometer).
5.8.7 Press **MENU** button when pressure reads 200 mmHg to save calibration setting.
5.8.8 Press and hold **MENU** button until the monitor beeps.
5.8.9 Turn the ProCare Monitor off.

5.9 Overpressure Verification

Note: To enter service mode press and hold the **CYCLE** button while pressing the **ON/OFF** button.

5.9.1 Remain in service mode.
5.9.2 Press **CYCLE** button until the **min** window shows 1.
5.9.3 Use the inflation bulb to inflate pressure until valve opens.
5.9.4 Record and verify pressure at which valve opens.

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5.9.5 Press **CYCLE** button so that the **min** window changes to a 2(Neonatal).
5.9.6 Use the inflation bulb to inflate pressure until valve opens.
5.9.7 Record and verify pressure at which valve opens.
5.9.8 Turn unit off.

5.10 Button Testing

5.10.1 Turn the Monitor on.
5.10.2 Record software revision as shown in the systolic and diastolic display.
5.10.3 Press **INFLATE/STOP** button.
5.10.4 Verify an **NIBP** determination has been initiated.
5.10.5 Block pump port and verify "**E80**" alarm.
5.10.6 Press **SILENCE** button verify alarm has been silenced.
5.10.7 Verify flashing red indicator of Silence.
5.10.8 Press the **SILENCE** button verify that alarm condition is removed.
5.10.9 Press **ALARM** button several times, verify unit cycles through all alarm settings (i.e SYS, DIA, SPO2).
5.10.10 Turn the Monitor off

5.11 LED Tests

5.11.1 Power on the *ProCare* Monitor.
5.11.2 During the power-up self-test verify all 7 segment LED display segments and all discrete LEDs (except CHARGING LEDs) illuminate and are the correct color.
5.11.3 Repeat power up cycle until all LED's are checked.

5.12 External DC Verification

5.12.1 Plug the DC power cable into the monitor.
5.12.2 Verify that the CHARGING indicator is illuminated.

5.13 NIBP Determination

5.13.1 Set NIBP Analyzer to Adult Mode: SYS/DIA = 120/80 MAP = 90 BPM = 80.
5.13.2 Press START/STOP button on the Monitor to begin determination.
5.13.3 Record and verify systolic, diastolic, map and heart rate from the monitor display.
5.13.4 Press **CYCLE** button to initiate a determination in "Auto BP" mode.
5.13.5 Record and verify systolic, diastolic, map and heart rate from the monitor display.

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5.13.6 Press **CYCLE** button until "**st**" is displayed on the HISTORY LED to initiate a determination in STAT mode.
5.13.7 Record and verify systolic, diastolic, map and heart rate from the monitor display.
5.13.8 Press **Start/Stop** button, end STAT mode.

5.14 NIBP Overpressure Verification

5.14.1 Restrict airflow through cuff hose port.
5.14.2 Press "**Inflate/Stop**" to begin NIBP determination.
5.14.3 Verify "**E80**" is displayed on the **SYSTOLIC** display and an audible alarm sounds.
5.14.4 Remove the air restriction.
5.14.5 Press "**Inflate/Stop**" and verify that the pump does not start.
5.14.6 Press the "**Silence**" button.
5.14.7 Press the "**Silence**" button again.
5.14.8 Verify the alarm condition is cleared from the **SYSTOLIC** display.

5.15 Temperature (Perform if equipped with Temp module)

The Temperature Simulator (TE 1811) for the Alaris System is available from Alaris Medical Systems, Inc. (619) 458-7000.

5.15.1 Connect Alaris temperature probe simulator to RJ-11 (temp) connector.
5.15.2 Insert temperature probe into the holder.
5.15.3 Remove temperature probe from the holder.
5.15.4 Set the probe simulator to 107.8° F.
5.15.5 Record and verify the reading in the TEMP display.
5.15.6 Set simulator to 80.2° F.
5.15.7 Record and verify the reading in the TEMP display.
5.15.8 Set simulator to 98.6° F.
5.15.9 Record and verify the reading in the TEMP display
5.15.10 Select B.P. press BROKEN PROBE on simulator, verify that the LED display on the UUT changes to four dashes, indicating a fault condition.

5.16 SpO2 (Perform only if equipped with SpO2 module)

5.16.1 Connect the appropriate SpO2 simulator and cable to the SpO2 connector.
5.16.2 Verify the unit displays a: Pulse value, Saturation value, Signal Strength Bar Graph.
5.16.3 Disconnect the SpO2 cable.
5.16.4 Verify the unit generates an "**E23**" alarm and speaker is sounding.
5.16.5 Press the **SILENCE** button.

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5.16.6 Verify the sound has stopped but the error display remains.
5.16.7 Re-connect the SpO2 sensor.
5.16.8 Verify the unit displays a: Pulse Value, Saturation value, Signal Strength bar Graph.

5.17 Printer Output Test (Perform only if equipped with Printer)

5.17.1 Load Thermal Paper into the print mechanism.
5.17.2 Press PRINT button.
5.17.3 Verify the printer outputs a record and print quality is good.

5.18 Remote Alarm

(Setup terminal emulator as follows: Open terminal emulator (such as Hyperterminal, ProComm Plus) Set communication port to 9600 baud, Data bit 8, Parity None, Stop Bit 1, Flow Control None).

5.18.1 Setup a DMM for continuity testing.
5.18.2 Connect DMM to pins 1 and 8 of the comm. port on the unit.
5.18.3 Verify “NO” continuity.
5.18.4 Turn unit on.
5.18.5 Verify continuity.
5.18.6 Press the START/ STOP button and start an NIBP determination.
5.18.7 Hold finger over the hose port and generate an “E80” alarm.
5.18.8 Verify “NO” continuity.
5.18.9 Turn unit off

5.19 Comunication Port Test

(Setup terminal emulator as follows: Open terminal emulator (such as Hyperterminal, ProComm Plus) Set communication port to 9600 baud, Data bit 8, Parity None, Stop Bit 1, Flow Control None).

5.19.1 Connect unit to a PC terminal emulator.
5.19.2 Turn unit on.
5.19.3 Type “ NC0!E”, press “Enter”.
5.19.4 Verify response from unit “ NC+!@”.
5.19.5 Verify that within 40 seconds the pump starts.
5.19.6 Type “ ND!5”, press “Enter”.
5.19.7 Verify response from unit “ ND+!A”.
5.19.8 Verify the pump stops.

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TEST RECORD (Appendix A)

Model #_____Serial # _____

Step	Description	Min	Max	Actual	Pass	Fail	N/A
5.6.	**Leakage**						
5.6.7	Leakage result (mmHg)	0	6				
5.7	**Pressure Transducer Verification**						
5.7.6	Pressure reading at 200mmHg, top display	197	203				
5.7.7	Pressure reading at 200mmHg, bottom display	197	203				
5.7.9	Pressure reading at 150mmHg, top display	147	153				
5.7.10	Pressure reading at 150mmHg, bottom display	147	153				
5.7.12	Pressure reading at 100mmHg, top display	97	103				
5.7.13	Pressure reading at 100mmHg, bottom display	97	103				
5.7.15	Pressure reading at 50mmHg, top display	47	53				
5.7.16	Pressure reading at 50mmHg, bottom display	47	53				
5.9	**Overpressure Verification**						
5.9.4	Overpressure threshold, Adult (mmHg)	305	325				
5.9.7	Overpressure threshold, Neonate (mmHg)	155	159				
5.10	**Buttons**						
5.10.2	Software revision in systolic display (top)						
5.10.2	Software revision in diastolic display (bottom)						
5.10.4	NIBP initiated						
5.10.5	"E80" displayed on SYSTOLIC display						
5.10.6	Audible alarm can be silenced						
5.10.7	"Silenced" LEDs ON						
5.10.8	Overpressure alarm can be cleared						
5.10.9	Alarm button is functioning						
5.11	**Display**						
5.11.2	All 7-segment LEDs light, correct color						
5.11.3	All discrete LEDs light, correct color						
5.12	**External DC Detection**						
5.12.2	Charging indicator LEDs light						

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Step	Description	Min	Max	Actual	Pass	Fail	N/A
5.13	**NIBP Determination**						
5.13.3	Systolic reading (mmHg)	107	133				
5.13.3	Diastolic reading (mmHg)	67	93				
5.13.3	MAP reading (mmHg)	85	95				
5.13.3	Heart rate reading (bpm)	76	84				
5.13.5	Systolic reading (mmHg)	107	133				
5.13.5	Diastolic reading (mmHg)	67	93				
5.13.5	MAP reading (mmHg)	85	95				
5.13.5	Heart rate reading (bpm)	76	84				
5.13.7	Systolic reading (mmHg)	107	133				
5.13.7	Diastolic reading (mmHg)	67	93				
5.13.7	MAP reading (mmHg)	85	95				
5.13.7	Heart rate reading (bpm)	76	84				
5.14	**NIBP Overpressure**						
5.14.3	"E80" displayed on SYSTOLIC display						
5.14.5	Pump will not start						
5.14.8	Overpressure alarm can be cleared						
5.15	**Turbo Temp Test**						
5.15.5	Temperature reading at 107.8F	107.5	108.1				
5.15.7	Temperature reading at 80.2	79.9	80.5				
5.15.9	Temperature reading at 98.6F	98.3	98.9				
5.15.10	Broken Probe alarm condition						
5.16	**SPO2**						
5.16.2	Pulse Value Displayed						
5.16.2	Saturation Value Displayed						
5.16.2	Bargraph Displayed						
5.16.4	"E23" displayed on SPO2 display						
5.16.6	Alarm is silenced, error display remains						
5.16.8	Pulse Value						
5.16.8	Saturation Value Displayed						
5.16.8	Bargraph Displayed						
5.17	**Printer Test**						
5.17.3	Printout is generated						

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Step	Description	Min	Max	Actual	Pass		
5.18	**Remote Alarm**						
5.18.3	No continuity from pin 1 to pin 8 (ohms)	1M					
5.18.5	Resistance between pin 1 and pin 8 (ohms)		50				
5.18.8	No continuity from pin 1 to pin 8 (ohms)	1M					
5.19	**Communication Port**						
5.19.4	"_NC+!@" is displayed on terminal						
5.19.5	Pump starts						
5.19.7	"_ND+!A" is displayed on terminal						
5.19.8	Pump stops						
5.0	**Safety Test**						
5.0.7	Temp Circuit Hi-Pot Test						
5.1.7	SPO2 Circuit Hi-Pot Test						
5.2.3	Temp Circuit Leakage Current (uA)						
5.3.4	SPO2 Circuit Leakage Current (uA)						

Tested By: _____ Date: _____

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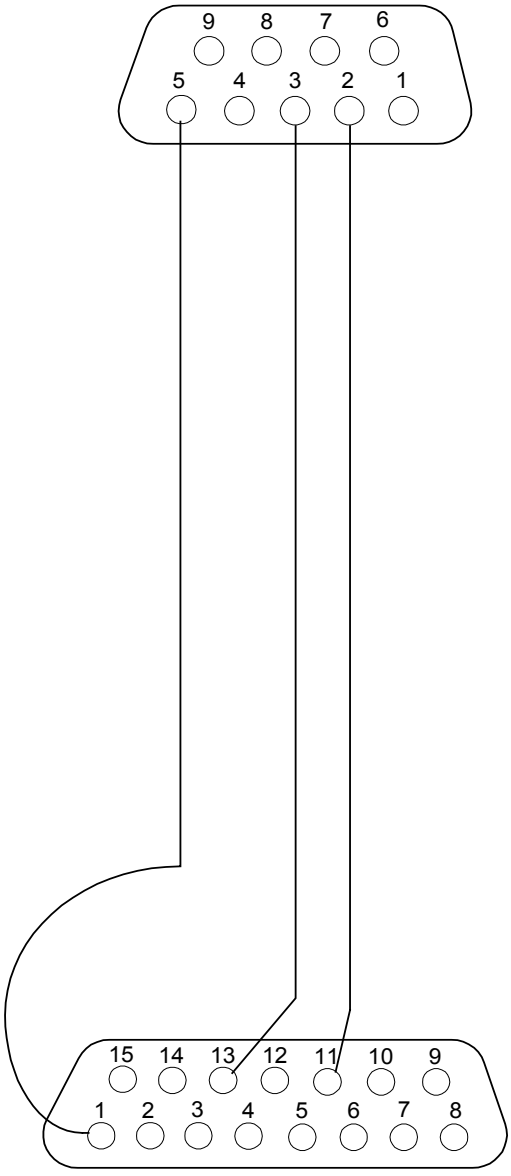
ProCare Service Test Procedure

Appendix B

9 PIN FEMALE (FRONT VIEW)



15 PIN MALE (FRONT VIEW)

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